UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,408	10/01/2003	Juergen Roemisch	6478.1446-01	5124

22852 7590 04/07/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,408	ROEMISCH ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18-62*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-62* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/632,974.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Attachment A*.

DETAILED ACTION

Status of claims

Claims 18-62 are pending.

The amendment filed 1/24/06 which cancels claims 1-17, and adds claims 18-62 has been entered. Also, applicants' request (filed 1/24/06) for extension of time of two months has been entered.

Essentially, support for the amended (independent) claim 18 can be found in paragraph [0016] where states that the substances recited in claim 18 refer to compounds functioning for storage of the isolated protease enzyme and for formulating pharmaceutical preparations. Thus, the pending claims 18-62 are drawn into the elected Group I, and thus, examined in this Office action.

Examiner has note that four SEQ ID NOs:1-4 have been disclosed in the parent application 09632974 (now Pat. No. 6670456).

Election/Restrictions

On page 14, the response filed 1/24/06 discusses the issue regarding inconsistency between the restriction requirement of this application and that of parent application 09632627 (now US Pat. No. 6677440) and that of 10701671. The applicants' argument has been fully considered but it is not persuasive. The restrictions of previous applications 09632974 and 10701671 and the restriction practice of the current application is not inconsistent. The same additional election requirement has been applied to both co-pending application No. 10701671 and the current application, which is supported by the statement set forth in pages 2-3 of Application No. 10701671. Examiner herein restates that additional election for one protein

stabilizer, e.g., divalent ions (inorganic compound), alcohols (organic agent) and protein (macro-biomolecule) is necessary as they are structurally distinct from one anther. It should be noted that the current invention is drawn to a composition comprising the protease activating blood clotting factor VII enzyme whereas the 6677440 drawn to a process of preparing the enzyme thereof; and thus, there would be different restriction practices between them.

In view of that one of functions of the claimed composition is used as a test reagent, the structurally different compounds/molecules, which previously are set forth in a "group" of the "protein stabilizer" (see the previous claim 9) having been subjected to the additional election in the Office action mailed 3/25/05, and now are set forth in new claims 18-62, are therefore examined upon due reconsideration.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 18-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to clearly and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 33 and 48 recite "composition comprising ....substance ... amino acids...". The speciation sets forth that "a substance which has bonds of different strength to the protease" (see paragraph [0028]). In view of this, the recitation is not apparent as to whether or not the protease covalently comprises the amino acids, or non-covalently associated with the protease in the composition. The claims depending from claims 18, 33 and 48 are also rejected.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims 18, 22, 24, 27 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi-Miura et al. (*J. Biochem.* (1996) 119, 1157-1165, *provided by the applicants' IDS*).

Choi-Miura et al. teach hyaluronan-binding protein (PHBP) polypeptide comprising the instant peptide sequences of SEQ ID NOs: 1-4 (see Figure 3) which has **100%** sequence identity to amino acid sequence of the coagulation Factor VII activating protease (see page 1, the last three lines of the specification). Choi-Miura et al. also teach a composition, i.e., an elution solution comprising the PHBP polypeptide and glycine (see "*Purification of PHBP*" section, page 1158, the left column).

It is of note that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Here, the Choi-Miura's PHBP protein and the coagulation Factor VII activating protease (this application) are structurally identical to each other; and thus, they should inherently have the same biological activity, e.g., a proteolytic enzymatic activity.

Thus, the above Choi-Miura et al. teachings inherently anticipate instant claims 18 and 24.

Since the PHBP contains arginine and cysteines (see Figure 3), the above teachings anticipate instant claims 22 and 27.

Since claim 31 recites "*the composition acts as a biological test reagent*", the recitation is considered to be an intended use which has no patentable eight to the claimed composition, the above Choi-Miura et al. teachings anticipate instant claim 32.

The applicants response to the rejection under 35 USC 102

On pages 18-19, the response filed 1/2/4/06 argues that the Choi-Miura et al. reference is not qualified for the anticipatory art as the reference does not provide details about the protein (protease) function, nor describes the composition comprising the claimed additional ingredients. Also, on the same page, the response argues that the reference dose not suggest that the claimed composition can be used as the biological test reagent.

The applicants' arguments are found to be unpersuasive because of the reasons discussion in the above rejection, and the reasons below.

The products of identical chemical composition cannot have mutually exclusive properties. Since the Choi-Miura's PHBP protein and the instant coagulation Factor VII activating protease are structurally identical to each other, the PHBP must inherently have the same biological activity of the claimed protease. The Choi-Miura's composition does comprise the component(s) in addition to the PHBP protein (enzyme), e.g., glycine at least (see above statement). The current invention is directed to the composition, the "*composition can be used as the biological test reagent*" is considered to be intended use and has little patentable weight to the claims.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-21, 22-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi-Miura et al. (*J. Biochem.* (1996) 119, 1157-1165, *provided by the applicants' IDS*) taken with Turner et al. (US Pat. NO. 5326558).

The teachings of Choi-Miura et al. applied to the instant claims 8, 22, 24, 27 and 32 have been discussed above, and also applied to claims 21, 30 and 28 herein. Note that the Choi-Miura's reference is applied to instant claim 31 because the above-mentioned composition also comprises albumin (as contaminant) (see page 1158, the left column, the last sentence of the 2nd paragraph).

Choi-Miura et al. do not expressly teach that the composition comprises complexing agent (e.g., EGTA or EDTA), and compound (e.g., aprotinin) for preventing protein degradation, and that the composition contains a reductant, e.g., dithiothreitol (DTT).

Yet, Choi-Miura et al. have discussed that the purified PHBP is suspectable to cleavage by proteolytic enzymes (see page 1162). It is well known that EGTA or EDTA and protease inhibitor compound, e.g., aprotinin, are routinely used in the protein purification procedure to prevent the purified protein/enzyme from proteolytic degradation. Turner et al. teach a cocktail comprising protease inhibitors (aprotinin, leupeptin, ethylene glycol-bis-tetraacetic acid (EGTA) which was added to the sample containing the protein that is subject to purification in order to minimize proteolysis (see column 13, lines 2-8), which is applied to instant claims 19-21, 23, 28-29.

One of ordinary skill in the art at the time the invention was made would have been motivated to formulate the composition with the above-mentioned protease inhibitory compounds. This is because Choi-Miura et al. already stated the problem regarding degradation of PHBP protein by the proteolytic enzyme, and because those protease inhibitory compounds are known and routinely used by the skilled artisan in order to reduce or minimize the proteolysis of the purified PHBP protein, which is evidenced by Turner et al. reference.

Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18 and 27-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of Application No. 10254662 (**662**). This is a provisional double patenting rejection because the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentable distinct from each other because of the reasons set forth below.

Claim 13 of application 662 discloses a pharmaceutical composition comprising coagulation factor VII-activating protease [FSAP], i.e., the protease activating blood clotting factor VII. On page 5, in the "*Example*" section for proliferation assay for FSAP, Application 662 teaches the composition (e.g., a FSAP buffer) comprises Trasylol which is an

injection/infusion formulation containing the active ingredient aprotinin. Application 662 claim 13 thus, is an obvious variation of instant claims 18 and 28-29.

Claim 13 of application 662 also teach (page 5) a composition comprising FSAP and a polypeptide (PDGFbb) which contains amino acids, e.g., arginine, cysteine. Claim 13 is thus obvious variation of instant claims 27 and 30. (claim 22 is not included here as claim 22 depends from claim 19 that is directed to the composition additionally comprises complexing agent of divalent ions).

Since the composition set forth in instant claim 31 regarding "*the composition acts as a biological test reagent*" is considered to be a intended use which has no patentable eight to the claimed composition, application 662 claim 13 is obvious variation of instant claim 32.

Thus, application 662 and claims 18 and 27-30 of 1application 10254662 are not patentably distinct from each other.

Claims 18-22, 24-26, 30-37, 39-41, 45-4-52, 54-56 and 60-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of Application No11/118,396 (**396**). This is a provisional double patenting rejection because the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentable distinct from each other because of the reasons set forth below.

Claim 31 of application 396 discloses a pharmaceutical composition comprising the protease activating blood clotting factor VII. On paragraph [0013], application 396 teaches

that said protease suffers from a rapid loss of activity; yet, the presence of albumin prevents the activity of the protease from decreasing. Thus, claim 31 is an obvious variation of instant claim 18 and 21.

On paragraphs [0057-0059], application 396 teaches that, in addition to albumin, the stabilizers for the protease are (i) sugar (claim 25), (ii) complexing agent for calcium ions, e.g., ethylenediamine tetraacetic acid (i.e., EDTA) (claims 19-20), and (iii) polyethylene glycol (claim 26), and amino acids (claims 22, 24 and 30). Claim 31 is therefore the obvious variation of instant claims 19-20, 22 and 24-26 and 30-31.

Since the composition set forth in instant claim 31 regarding "*the composition acts as a biological test reagent*" is considered to be a intended use which has no patentable eight to the claimed composition, application 396 claim 31 is obvious variation of instant claim 32.

In view of that claim 33 and the dependent claims thereto are directed to composition comprising **proenzyme** of said protease, and application 396 claim 31 is directed to the composition comprising a mixture of the protease and its proenzyme, for the same reasons stated above, application 396 claim 31 disclose the common subject matter to that of instant claims 33-37, 39-41 and 45-47.

Further, in view of that claim 48 and the dependent claims thereto are directed to composition comprising the protease and the **proenzyme** of said protease, and application 396 claim 31 is directed to the composition comprising a mixture of the protease and its proenzyme, for the same reasons stated above, application 396 claim 31 disclose the common subject matter to that of instant claims48-52, 54-56 and 60-62.

Thus, claims 18-22, 24-26, 30-37, 39-41, 45-4-52, 54-56 and 60-62 of Application 11/118,396 are obvious variation of the instant claim 13 and they are not patentably distinct from each other.

Applicant's response to the Double-patenting rejection

On page 19, the response filed 1/24/06 requests abeyance of the obvious-type double patenting rejection until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242 or 703-872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel Wei Liu, Ph.D.
March 27, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER

ISO 9001 CERTIFIED

integrated proteomics soluti

Unusual Amino Acids

Analogs of Benzoic Acid
Analogs of Phenylalanine and Tyrosine
Miscellaneous Aromatic Amino Acids
Analogs of Proline
Analogs of Tryptophan
Miscellaneous Heterocyclic Amino Acids
Analogs of Arginine and Lysine
Analogs of Alanine, Glycine, Valine, and Leucine
Analogs of Aspartic and Glutamic Acids
Analogs of Cysteine and Methionine
Analogs of Serine, Threonine, and Statine
Miscellaneous Aliphatic Amino Acids
β-Amino Acids
N-α-Methyl Amino Acids
Amino Alcohols

Attachment A.

Copyright © 2002-2006 AnaSpec, Inc. All rights reserved. | 65.39.186.246 (USA)